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CDC HAN INFOService

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HANINFO-00354

Investigational Drug Available Directly from CDC for the Treatment of Free-Living Ameba Infections

Summary

CDC now has an expanded access investigational new drug (IND) protocol in effect with the Food and Drug Administration (FDA) to make miltefosine available directly from CDC to clinicians for treatment of free-living ameba (FLA) infections in the United States.

Background

Infections caused by FLA are severe and life-threatening. These infections include primary amebic meningoencephalitis (PAM) caused by *Naegleria fowleri** and granulomatous amebic encephalitis caused by *Balamuthia mandrillaris*† and *Acanthamoeba* species.§ Although several drugs have in vitro activity against FLA, mortality from these infections remains greater than 90% despite treatment with combinations of drugs.

Miltefosine is a drug used to treat leishmaniasis and also has shown in vitro activity against FLA (1), but as an investigational drug, it has not been readily available in the United States. With CDC assistance, however, miltefosine has been administered in combination with other drugs since 2009 for FLA infections as single-patient emergency use with permission from the Food and Drug Administration. Although the number of *B. mandrillaris* and *Acanthamoeba* species infections treated with a miltefosine-containing regimen is small, it appears that a miltefosine-containing treatment regimen does offer a survival advantage for these usually fatal infections (2). Miltefosine has not been used successfully to treat a *Naegleria* infection, but the length of time it has taken to import miltefosine from abroad has made timely treatment of fulminant *Naegleria* infections with miltefosine difficult.

CDC now has an expanded access IND protocol in effect with the Food and Drug Administration to make miltefosine available directly from CDC for treatment of FLA in the United States. The expanded access IND use of miltefosine for treatment of FLA is partly supported by 26 case reports of FLA infection from around the world during the period of 2008–2012 in which miltefosine was part of the treatment regimen (Unpublished data, Division of Foodborne, Waterborne, and Environmental Diseases, National Center for Emerging and Zoonotic Infectious Diseases, CDC, 2013). Miltefosine is generally well-tolerated, with gastrointestinal symptoms as the most commonly reported adverse effects.

Recommendations

Clinicians who suspect they have a patient with FLA infection who could benefit from treatment with miltefosine should contact CDC to consult with an FLA expert. See the For More Information section below for information on contacting a CDC FLA expert.

For More Information

- For diagnostic assistance, specimen collection guidance, specimen shipping instructions, treatment recommendations, and information on obtaining miltefosine from CDC, clinicians should contact the CDC Emergency Operations Center at 770-488-7100 to request to speak to an FLA expert.
- For more information on diagnostic assistance specimen collection guidance and specimen shipping instructions, see <http://www.cdc.gov/parasites/naegleria/diagnosis-hcp.html>.
- For *Naegleria fowleri* treatment recommendations, see <http://www.cdc.gov/parasites/naegleria/treatment-hcp.html>.
- For the MMWR Notice to Readers on this topic, see http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6233a4.htm?s_cid=mm6233a4_w.

References

1. Schuster FL, Guglielmo BJ, Visvesvara GS. In-vitro activity of miltefosine and voriconazole on clinical isolates of free-living amebas: *Balamuthia mandrillaris*, *Acanthamoeba* spp., and *Naegleria fowleri*. *J Eukaryot Microbiol* 2006;53:121–6.
2. Cope JR, Roy SL, Yoder JS, Beach MJ. Improved treatment of granulomatous amebic encephalitis and other infections caused by *Balamuthia mandrillaris* and *Acanthamoeba* species [Poster]. Presented at CSTE Annual Conference, Pasadena, CA, June 9–13, 2013. Available at <http://www.cste2.org/confpresentations/uploadedfiles/cste%202013%20miltefosine%20Poster%20final.pdf>.

Endnotes

* Additional information available at <http://www.cdc.gov/parasites/naegleria>.

† Additional information available at <http://www.cdc.gov/parasites/balamuthia>.

§ Additional information available at <http://www.cdc.gov/parasites/acanthamoeba>.

The Centers for Disease Control and Prevention (CDC) protects people's health and safety by preventing and controlling diseases and injuries; enhances health decisions by providing credible information on critical health issues; and promotes healthy living through strong partnerships with local, national, and international organizations.

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DHEC contact information for reportable diseases and reporting requirements

Reporting of unusual clusters of illness is consistent with South Carolina law requiring the reporting of diseases and conditions to your state or local public health department (State Law # 44-29-10 and Regulation # 61-20). The DHEC 2013 List of Reportable Conditions is available at <http://www.scdhec.gov/health/disease/reportables.htm>

Federal HIPAA legislation allows disclosure of protected health information, without consent of the individual, to public health authorities to collect and receive such information for the purpose of preventing or controlling disease (HIPAA 45 CFR §164.512).

Regional Public Health Offices – 2013

Mail or call reports to the Epidemiology Office in each Public Health Region.

LOW COUNTRY PUBLIC HEALTH REGION

Berkeley, Charleston, Dorchester
4050 Bridge View Drive, Suite 600
N. Charleston, SC 29405
Phone: (843) 953-0043
Fax: (843) 953-0051
Nights / Weekends: (843) 441-1091

Beaufort, Colleton, Hampton, Jasper
219 S. Lemacks Street
Walterboro, SC 29488
Phone: (843) 549-1516
Fax: (843) 549-6845
Nights / Weekends: (843) 441-1091

Allendale, Bamberg, Calhoun, Orangeburg
PO Box 1126
1550 Carolina Avenue
Orangeburg, SC 29116
Phone: (803) 268-5866
Fax: (843) 549-6845
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MIDLANDS PUBLIC HEALTH REGION

Kershaw, Lexington, Newberry, Richland
2000 Hampton Street
Columbia, SC 29204
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Nights / Weekends: (888) 554-9915

Chester, Fairfield, Lancaster, York
PO Box 817
1833 Pageland Highway
Lancaster, SC 29720
Phone: (803) 286-9948
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Aiken, Barnwell, Edgefield, Saluda
222 Beaufort Street, NE
Aiken, SC 29801
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Fax: (803) 643-8386
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PEE DEE PUBLIC HEALTH REGION

Chesterfield, Darlington, Dillon, Florence, Marlboro, Marion
145 E. Cheves Street
Florence, SC 29506
Phone: (843) 661-4830
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Clarendon, Lee, Sumter
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105 North Magnolia Street
Sumter, SC 29150
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Georgetown, Horry, Williamsburg
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Fax: (843) 365-0085
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UPSTATE PUBLIC HEALTH REGION

Anderson, Oconee
220 McGee Road
Anderson, SC 29625
Phone: (864) 260-5801
Fax: (864) 260-5623
Nights / Weekends: (866) 298-4442

Abbeville, Greenwood, Laurens, McCormick
1736 S. Main Street
Greenwood, SC 29646
Phone: (864) 227-5947
Fax: (864) 942-3690
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Cherokee, Greenville, Pickens
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200 University Ridge
Greenville, SC 29602-2507
Phone: (864) 372-3133
Fax: (864) 282-4373
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(continued)

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DHEC Bureau of Disease Control

Division of Acute Disease Epidemiology
1751 Calhoun Street
Box 101106
Columbia, SC 29211
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